# Predicting the learning curve and failures of total percutaneous endovascular aortic aneurysm repair

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***Introduction:*** **Percutaneous endovascular aneurysm repair (PEVAR) has been shown to be feasible; however, technical success is variable, reported to be between 46.2% and 100%. The objective of this study was to quantify the learning curve of the PEVAR closure technique and identify predictors of closure failure.**

***Methods:*** **We reviewed patient- and procedure-related characteristics in 99 consecutive patients who underwent PEVAR over a 30-month period in a single academic institution. A suture-mediated closure device (Proglide or Prostar XL) was used. Forward stepwise logistic regression was used to investigate associations between the failure of the closure technique and a number of patient and operative characteristics. To ensure objective assessment of the learning curve, a time-dependent covariate measuring time in calendar quarters was introduced in the model. Poisson regression was used to model the trend of observed failure events of the percutaneous technique over time.**

***Results:*** **Overall PEVAR technical success was 82%. Type of closure device ($P < .35$), patient's body mass index ($P < .86$), type of anesthesia ($P < .95$), femoral artery diameter ($P < .09$), femoral artery calcification ($P < .56$), and sheath size as measured in Fr ($P < .17$) did not correlate with closure failure rates. There was a strong trend for a decreasing number of failure events over time ($P < .007$). The average decrease in the odds of technical failure was 24% per calendar quarter. The predicted probability of closure failure decreased from 45% per patient at the time of the initiation of our PEVAR program to 5% per patient at the end of the 30-month period. There were two postoperative access-related complications that required surgical repair. Need for surgical cutdown in the event of closure failure prolonged the operative time by a mean of 45 minutes ($P < .001$). No groin infections were seen in the percutaneous group or the failed group.**

***Conclusions:*** **Technical failure can be reduced as the surgeon gains experience with the suture-mediated closure device utilized during PEVAR. Previous experience with the Proglide device does not seem to influence the learning curve. (J Vasc Surg 2013;57:72-6.)**

Advances in technology combined with smaller sheath sizes to deliver large stent grafts have transformed abdominal aortic surgery over the last decade. Endovascular exclusion (EVAR) has become the first-line therapy in treating abdominal aortic aneurysms (AAAs), and now percutaneous EVAR (PEVAR) is increasingly becoming more popular than surgical femoral cutdown (FC-EVAR) for stent graft delivery. Multiple prospective studies[1-8] and one randomized study[9] have shown the feasibility of PEVAR since its introduction in 1999.[10] PEVAR has been shown to reduce groin wound infections and lymphoceles as well as hematomas. On the other hand, PEVAR technical success has been reported to be between 46% and 100%[2-10] in the literature. Large sheath size,[2-4,6] obesity,[2-4,6] and femoral calcifications[1-2,6] have been reported as predictors of PEVAR technical failure. Operator's inexperience has been alluded to as a contributing factor for decreasing technical success.[5] Only one study reports the impact of surgeon experience on PEVAR outcomes; this study demonstrated an odds ratio of 43.2 ($P < .001$) for early conversion to FC-EVAR in the hands of inexperienced operators (<30 interventions).[1]

The purpose of our study was to examine the learning curve over time as well as identify predictors of failure since the initiation of our PEVAR program in March of 2009.

## METHODS

Patient- and procedure-related characteristics were reviewed in the first 99 consecutive patients who underwent PEVAR (abdominal and thoracic) over a 30-month period in a single academic institution since March of 2009. Retrospective review of the data was performed at the Michael E. DeBakey Veterans Affairs Hospital in Houston, TX. Institutional Review Board approval from both Baylor College of Medicine and the Michael E. DeBakey Veterans Affairs hospital was obtained. All the cases were performed in the operating room under either general, regional, or local anesthesia with moderate sedation. All patients received preoperative intravenous antibiotics and a sterile

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prep from the chest to the knees. Data were collected on patients that were treated using femoral sheath size ≥12 Fr. Primary end points were technical success of percutaneous access, FC-EVAR conversion to achieve hemostasis, type of femoral artery calcifications, advertent outcomes of percutaneous failure, and causes of failure.

**Patient selection.** Since the initiation of the PEVAR program in March of 2009, all patients undergoing aneurysm exclusion were considered for PEVAR. The only exclusion was the presence of common femoral artery aneurysm requiring repair and the need for femoral artery reconstruction such as endarterectomy with patch angioplasty. Obesity, femoral calcifications, previous groin surgery, type of stent graft device, and large sheath (>20 Fr) were not considered as a contraindication for PEVAR. Femoral calcification was reported based on its distribution: anterior, posterior, or circumferential calcifications. In addition to collecting data on body mass index (BMI), information on common femoral artery (CFA) depth from the skin was collected. This was done because BMI did not reflect the accurate depth of the femoral vessels due to different fat distribution among different patients. The depth was measured as a vertical line from the anterior abdominal wall to the CFA as described previously by Smith et al.[7] Femoral artery diameter was obtained by measuring the inner diameter based on the preoperative computed tomography angiography images.

**Device and technique.** Ultrasound-guided access of bilateral CFA's using Sonosite Titan ultrasound (Sonosite, Bothell, Wash) was performed in all the cases. All patients were heparinized during the procedure to a goal activated clotting time of >250 seconds. Protamine dose, either full or half reversal relative to the heparin dose, was administered at the end of the surgery. Two different suture-mediated closure devices were used for the PEVAR cases depending on the operator. Either the 6F Perclose Proglide or the 10F Prostar XL was used (Abbott Vascular, Redwood City, Calif). The Prostar XL was used exclusively by one of the authors (C.F.B.); the remaining authors are Proglide users. Only one Prostar XL is used per femoral vessel or two Proglides, regardless of sheath size. Since the Proglide device has a preknotted suture and is routinely used for other endovascular peripheral interventions, we examined the data to see if prior experience affected the learning curve during PEVAR in comparison to the Prostar device. At the time of the PEVAR program initiation, none of the authors had any prior experience with this technique using the Proglide device. One of the authors (C.F.B.) had some experience with the Prostar device, but it was limited to less than five cases. However, all of the surgeons had tremendous prior experience with Proglide (>100 cases) from using it during other endovascular peripheral interventions.

Our "preclose" technique for Prostar XL[4] and Proglide[2] deployment and closure is similar to what has been described by other authors except for a few modifications. Since all femoral vessels were accessed using the ultrasound, angiography to confirm access location was not routinely performed. The CFA was accessed just above the profunda artery bifurcation in the middle of a healthy segment (Fig 1). Blunt dissection was performed with a hemostat around the sheath prior to any closure device deployment. The sutures were placed to the side and covered with heparinized saline-soaked gauze. At the end of the surgery, the smaller sheath was removed first, followed by the larger sheath. Most times, we start slowly infusing protamine during this process. The suture is gently cinched down around the sheath by applying tension and countertension to avoid pulling the sutures through the arteriotomy. The sutures were continuously irrigated during this process. Gentle pressure on the access site was applied until all the protamine was infused, and activated clotting time returned to normal level. All patients laid flat in the recovery room for 1 to 2 hours; both groins were examined prior to discharge to the floor.

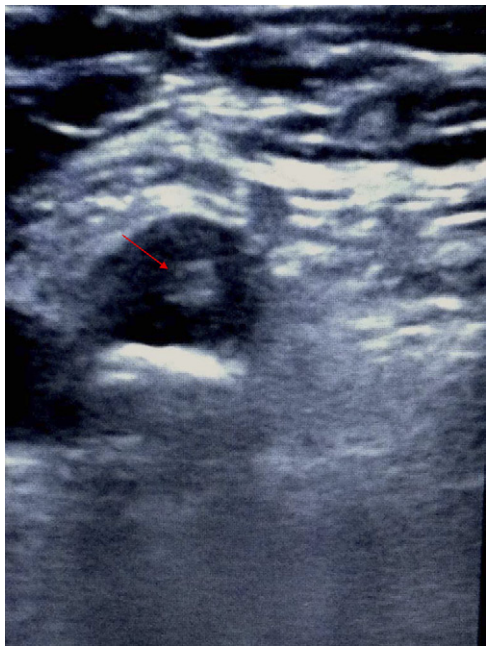

**Fig 1.** Ultrasound is used to access the common femoral artery in the middle of a healthy segment. *Arrow* pointing to tip of the needle.

**Statistics.** Forward stepwise logistic regression was used to investigate the association between failure of the closure technique and a number of patient and operative characteristics. To ensure objective assessment of the learning curve, a time-dependent covariate measuring time in calendar quarters since the beginning of the PEVAR program was introduced in the model. Poisson regression was used to model the trend of observed failure events of the percutaneous technique over time. Analysis was performed with Stata IC version 11.2 (StataCorp, College Station, Tex).

## RESULTS

Ninety-nine patients underwent PEVAR during the study period. The charts were reviewed retrospectively to assess the learning curve needed to reduce technical failure of the percutaneous closure. All 99 aneurysms were successfully treated with an endovascular stent graft. Most of these aneurysms were located in the infrarenal aorta (81 cases, 81.8%); 13 were either isolated iliac aneurysms or with an infrarenal aneurysm, and five were thoracic aneurysms. The majority of the PEVAR cases were done under general anesthetic (69, 69.7%), 18 (18.2%) under spinal anesthesia, and 12 (12.1%) under local/sedation.

The overall technical success rate for the percutaneous closure was 81.8% (81 cases out of 99). The majority of the cases, 16 cases, were intraoperative conversion to FC-EVAR to achieve hemostasis. All of these cases except for two were repaired primarily. The remaining two cases required a small bovine patch to repair the femoral artery. Most of the failures were either due to suture partially pulling through the arteriotomy or the inability to push the knot all the way down to the level of the arteriotomy. There were two postoperative access-related complications that required surgical repair. One was common femoral artery thrombosis on postoperative day 1 that required thrombectomy and patch angioplasty, and the other was open repair for pseudoaneurysm on postoperative day 2. Need for surgical cutdown in the event of closure failure prolonged the operative time by a mean of 45 minutes ($P < .001$). No groin infections were seen in the percutaneous group or the failed group.

Type of closure device ($P < .35$), BMI ($P < .86$), use of a hydrophilic sheath ($P < .69$), type of anesthesia ($P < .95$), femoral artery diameter ($P < .09$), femoral artery calcification ($P < .56$), and sheath size as measured in Fr ($P < .17$) did not correlate with closure failure rates. The mean BMI was 27.45 (range, 18-42.5), with 33 cases with BMI ≥30 and five cases with BMI ≥40. The distance from skin to femoral vessels did not affect technical failure ($P < .24$). The mean distance was 3.9 cm (range, 1.5-10.2 cm). We used six different stent grafts to treat the 99 aneurysms. The right common femoral artery median sheath size used was 18 Fr (range, 12-24) and 16 Fr (range, 12-24) for the left common femoral artery.

The percutaneous failure rate over time was then examined. We found a strong trend for decreasing failure rate over time ($P < .007$). The average decrease in the odds of technical failure was found to be 24% per calendar quarter. The probability of closure failure per patient over time was also examined. The predicted probability of closure failure decreased from 45% per patient at the time of the initiation of our PEVAR program to 5% per patient at the end of the 30-month period. At the time of writing this article, it decreased to <3%. The learning curve appeared to be steepest during the first 18 months (Fig 2). Our data showed that prior experience with the Proglide device does not affect the learning curve. Actually, the learning curve for the Proglide device is almost identical to the Prostar curve (Fig 3).

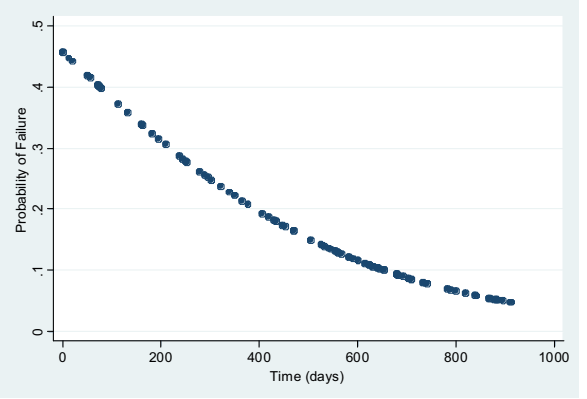


**Fig 2.** Predicted probability of percutaneous failure over time. The curve is steepest during the first 18 months.

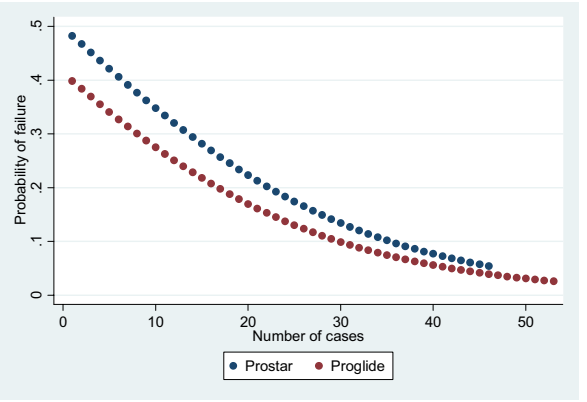


**Fig 3.** Predicted probability of device failure over time (Prostar in the *blue curve* and Proglide in the *red curve*). Prior experience with Proglide use does not offer any advantage.

## DISCUSSION

Total PEVAR is gaining popularity among surgeons and interventionalists. Our study revealed similar findings to a recently published data that obesity, large sheath size (in our study, large and small sheath), and femoral artery calcifications are not associated with percutaneous failure.[11] The most striking finding in our study was the demonstration of increasing technical success over time. Currently, we tell our patients in clinic evaluated for PEVAR that there is <3% risk of conversion to open femoral repair. Groin complications after FC-EVAR have been reported to be >20% in multiple studies.[3,7,9] In order to achieve technical success of >80%, we found that at least 15 cases are needed, and approximately 30 cases are needed to achieve technical success >90% (Fig 3). It was noted previously by Torsello et al, that an operator is considered experienced after deploying >30 Prostar devices.[1,9] However, this relationship was never measured in percentile or

numbers. Dosluoglu et al noted that there was no learning curve using the Proglide device in a larger sheath if the surgeon had prior experience with the device in closing smaller sheaths.[12] Interestingly, we found that prior experience with the Proglide closure device did not confer any advantage. Our explanation is that the percutaneous technical success is multifactorial and depends on proficiency in different steps: ultrasound-guided access, adequate suture deployment, and knowledge of the closure device as well as the closure technique. In addition, all these procedures were performed in a single academic institution where resident, fellows, and attendings participated to learn the percutaneous closure technique. Clearly, the operator expertise in the above-mentioned steps varied, but it was impossible to factor it into this study, except for the number of cases performed by each operator.

We will share some of the technical points that we learned over time that we believe helped us achieve the current technical success of >97%.

Several studies have demonstrated the importance of ultrasound-guided femoral artery access to improve technical success as well as to decrease the conversion rate to open femoral artery repair.[4,11,13] This study cannot prove that, since ultrasound-guided femoral access is routinely performed for all endovascular cases done at our institution regardless of sheath size or type of procedure. However, we are advocates of ultrasound use for several reasons. Ultrasound allows the operator to access the CFA in the center of a healthy segment to allow the needles and sutures to be successfully deployed. This is crucial in patients with unusual calcifications and anatomy. In addition, the CFA is always accessed just above where the profunda artery bifurcates. The femoral head is not used as a marker nor is a diagnostic angiogram performed to confirm appropriate access. If the main body of the device can be placed from either side, we tend to place the large sheath in the CFA with the lowest bifurcation to stay away from the inguinal ligament. Sutures getting tangled in the inguinal ligament can be a source of technical failure.[11] The subcutaneous tissue around the sheath should be dissected circumferentially prior to the "preclose" technique all the way down to the femoral vessels. This is particularly important in scarred groins and patients with high CFA bifurcation where access is most likely near or through the inguinal ligament. We do not have enough numbers of groins with previous surgeries in our data to make any sound conclusions, but we were able to achieve hemostasis in closing a 22 Fr arteriotomy in a patient with two prior groin surgeries. Prior groin surgery was present in 6.8% of the PEVAR cases in one study, but it did not affect technical success.[11] Serial dilations of the arteriotomy was not routinely performed in our study.

Starnes et al[4] recommended closing the arteriotomy with the larger sheath first to have the contralateral access available in case an endovascular balloon is needed for proximal control if conversion to open repair is needed. We routinely close the smaller sheath first and start infusing protamine slowly while closing the larger arteriotomy. When pulling down the sutures, it is crucial to put tension and countertension to avoid pulling the sutures. This takes time and judgment to know how much tension is needed to pull the sutures down. Irrigating the sutures during this process helped slide the knot down.

Need for surgical cutdown in the event of closure failure prolonged the operative time by a mean of 45 minutes ($P < .001$). Blood loss and transfusion was not significant. We typically do not remove the wire access unless we are satisfied with the hemostasis. If conversion to FC-EVAR is performed, we place a sheath and sometimes an occlusive balloon to achieve hemostasis while femoral exposure is being performed. No groin infections were seen in the percutaneous group or the failed group.

Some authors avoid using the Prostar device because the suture is braided and puts it at risk for infection.[14] All our procedures were performed in the operating room under strict sterile conditions, and all patients received intravenous antibiotics before and after surgery.

We believe training in the animal laboratory or attending training courses might help reduce the learning curve; however, our study did not look at these factors. This could be an area for future research. Another limitation to our study was the retrospective analysis of the data.

## CONCLUSIONS

Technical failure can be reduced over time, as the surgeon gains experience with the suture-mediated closure device utilized during PEVAR. Previous experience with the Proglide device does not seem to influence the learning curve. Currently, we tell our patients that there is <3% risk of conversion to open FC-EVAR with PEVAR.

## AUTHOR CONTRIBUTIONS

Conception and design: CB
Analysis and interpretation: CB, NB, GP, HC, TP, PL, PK
Data collection: CB, NB, GP, HC, TP, PL, PK
Writing the article: CB
Critical revision of the article: CB, NB, GP, PL, PK
Final approval of the article: CB
Statistical analysis: CB, NR, PK
Obtained funding: Not applicable
Overall responsibility: CB

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